

Remarks

Claims 1-43 were pending in the application. Misnumbered claims 23-43 have been renumbered as claims 26-46, their internal dependencies corrected, and claim 2 cancelled. Hence claims 1 and 3-46 remain for examination. Reconsideration of the rejection is respectfully requested.

§ 112 Rejection

Claim 15 was rejected under 35 U.S.C. § 112, because “the therapeutic” in line 3 of that claim lacked antecedent basis. That language has been amended to change it to “a therapeutic” and overcome the rejection.

§ 102 Rejection

Claims 1-4, 7-16 and 20-21 were rejected as being anticipated by U.S. Patent No. 5,527,534 (hereinafter “Myhling”). Myhling was said to disclose an interlabial delivery device comprising a delivery material retained between the labia and which carries a therapeutically or diagnostically effective amount of a therapeutic or diagnostic agent. These features were alleged to be shown at column 1, lines 1-10, and lines 17-22 of the Myhling patent. Applicants request reconsideration of this rejection, because Myhling discloses an *intravaginal* delivery device instead of an *interlabial* delivery device.

The Myhling patent repeatedly emphasizes that the disclosed invention is a method of administering a pharmaceutical agent “via the vaginal cavity” (column 1, line 11). The primary object of the invention is said to be provision of a *vaginal sponge* (column 3, lines 20-23, emphasis supplied). The Summary of the Invention notes that the “present invention now provides a removable, premoistened vaginal sponge...” (column 3, lines 61-62), and that the invention is a “*vaginal tampon*” (column 4, line 33, emphasis supplied). The vaginal tampon or sponge is used “for sustained release of a liquid containing carrier and an active agent for a prolonged period of time to a targeted site *within the vagina* (column 5, lines 7-10, emphasis supplied). The internal placement of the vaginal tampon inside the vagina against the cervical os is shown in FIG. 4 of the Myhling patent.

In contrast, claim 1 of the pending application calls for an *interlabial* device. As shown in FIGS. 1 and 2, and described in the accompanying text on pages 10-11 of the specification, an

interlabial device fits between the external labia of the wearer, not internally within the vagina as in the Myhling patent. The claimed invention is not an internal vaginal tampon of the type shown in the Myling patent. Rather it is an externally retained device that is frictionally engaged between the labia of the wearer.

Claim 1 has been amended to clarify the structure of the pad, which has a minor portion and a major portion, wherein the minor portion of the pad tapers to facilitate insertion between the labia and retention in the interlabial space. These minor and major portions facilitate retention of the device between the labia minora and majora. Myhling does not disclose such a structure, and therefore does not anticipate claim 1, or any claims that depend from it.

§ 103 Rejection

Claims 5 and 6, 17-19 and 22-46 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Myhling in view of U.S. Patent No. 3,983,873 (hereinafter "Hirschman"). Since the features of claim 5 have been introduced into claim 1, this rejection is understood as applying to amended claim 1, and will be addressed with respect to amended claim 1.

Claim 1 calls for an interlabial delivery device to be a pad having a minor portion and a major portion, the minor portion having a cross-sectional area smaller than a cross-sectional area of the major portion and wherein the minor portion is tapered to facilitate insertion between the labia and retention in the interlabial space. The Myhling patent does not disclose such a structure, which is designed to retain the pad between the labia external to the vagina. It would not be obvious to modify the medicated tampon of Myhling to be a specialized pad having the claimed configuration because, as noted above, it is a specific object of the Myhling tampon to be placed *intravaginally*. It would not be obvious to modify the Myhling tampon to assume a configuration that is suitable for external retention, because that would defeat and frustrate the repeatedly expressed purpose of the Myhling tampon, which is to provide for *intravaginal* placement and administration of a drug.

Moreover, the cited references neither disclose nor suggest external retention of a medicated pad between the labia of a subject. Myhling never mentions such an application, and the Hirschman patent is completely silent about such a device. It is only the applicants' own disclosure that provides the suggestion for configuring a medicated pad for external retention between the labia of a patient. This new device for the first time allows the targeted application

of medication to the labia and other external female genitalia. Since the prior art does not disclose or suggest such a device, the cited prior art does not establish a prima face case of obviousness. Claim 1 is therefore allowable.

Claim 4 calls for the pad to be elongated to conform to an internal shape of the labia. Such a configuration would not be obvious in view of the cited references, because it would contravene the purpose of Myhling, which is intravaginal placement of the sponge delivery system. Configuring a pad to conform to the shape of the labia would not be obvious in view of Myhling's teaching that the device should be placed *inside the vagina*.

Claim 5 calls for the pad to have an external cavity in the surface of the pad, wherein substantially all the diagnostic or therapeutic agent is contained in that external cavity. See FIG. 28 of the specification for an example of such a pad. In contrast, the Myhling patent discloses multiple internal pores throughout which the agent is distributed. Hirschman does not disclose any medication in the pad, much less can it be said to disclose or suggest such medication substantially completely in an external cavity of the pad.

Claim 6 calls for the major axis of the pad to be of a sufficient size to retain the device substantially completely external to a vaginal orifice. Such a configuration could not be said to be obvious in view of Myhling, because as already noted Myhling teaches the importance of achieving *intravaginal* placement and administration. It would contravene and frustrate the purpose and function of Myhling to configure a pad for retention substantially completely *external* to a vaginal orifice.

Claims 7-14 depend from allowable claims, and are allowable for at least that reason.

Method claim 15 was said to be anticipated by Myhling, because that patent was said to disclose treating a disease with a device configured to be retained between the labia of a subject in an interlabial space. However, as noted above, Myhling does not disclose such a method. In contrast to the claimed external placement of the pad outside the vagina, Myhling repeatedly and exclusively teaches the internal *intravaginal* placement of a delivery device. None of the prior art even demonstrates an appreciation of the problem being solved in claim 15 (retention of previously applied medication to the external genitalia, or retention of medication that has been intravaginally administered), much less could it be said to disclose or suggest the claimed method. The only disclosure or suggestion for the claimed method comes from the applicants'

own specification, and that specification can not be used to reject the pending claims. The cited references do not establish a prima facie case of obviousness of the claimed method.

Claim 16 states that the device is placed and retained substantially completely external to a vaginal orifice, which as previously noted would defeat and frustrate the function and purpose of the Myhling patent.

Claims 17-20 are patentable for reasons already discussed in connection with earlier claims.

Claim 21 states that the method is a method of systemically delivering the agent translabially. The Myhling patent only discusses intravaginal administration, while the Hirschman patent does not describe administration of any agent at all. The cited references do not establish a prima facie case of obviousness with respect to this claim.

Claim 22 is a method of administering a drug comprising inserting a pad impregnated with the drug into the subject's interlabial space, and positioning the pad against the subject's external vaginal orifice, wherein the pad is devoid of corners and flat surfaces. This claim was said to be obvious in view of the combination of Myhling and Hirschman. In particular, FIG. 2 of Myhling was said to disclose a pad that was devoid of corners or flat surface intermediate its ends. As already noted, the cited references neither disclose nor suggest a method of administering a drug by placing a pad against a subject's external vaginal orifice. Moreover, claim 22 has been amended to state that the pad is devoid of corners and flat surfaces, instead of being devoid of corners and flat surfaces intermediate its ends. The subject matter of claim 22 is neither disclosed nor suggested by the prior art, and should be allowed.

Claim 24 states that the pad is elongated, and when placed in the interlabial space extends completely external to the vaginal orifice. This arrangement contravenes the teaching of Myhling's intravaginal placement, and it would not be obvious to modify Myhling in this manner.

Claim 27 states that the pad includes a recess that extends along an exterior surface of the pad and in which the drug is placed. None of the cited references disclose such a structure. Although Myhling discloses pores of a tampon that contain medication, a pore is a small opening that does not extend along an exterior surface of the pad.

Claim 28 is directed to a method for treating a symptom of a subject, comprising positioning an interlabial elongated absorbent pad such that the pad is retained between the labia

external to the subject's vaginal orifice, and retaining the pad in the interlabial space. This method was said to be obvious in view of Myhling as modified by Hirschman, because Myhling was said to disclose treating a symptom by positioning an interlabial absorbent pad external to the subject's vaginal orifice, as shown in FIG. 4 of that patent. However, FIG. 4 of Myhling does not show positioning a pad *external* to the subject's vaginal orifice as alleged in the Office action. Instead it shows the device placed inside the vagina, against the vaginal cervix. See column 14, lines 11-13 of the Myhling patent. The prior art therefore does not establish a prima facie case of obviousness with respect to claim 28.

The subject matter of claims 29-43 is neither disclosed nor suggested by the cited references.

Claim 44 calls for a cavity in the external surface of the pad to be a recess in the exterior surface of the minor portion of the pad. None of the cited references disclose or suggest such an arrangement, and they therefore fail to establish a prima facie case of obviousness with respect to this claim.

A prima facie case of obviousness is similarly absent with respect to claims 45-46.

Conclusion

Since the cited references do not disclose or suggest the claimed invention, a Notice of Allowance should be issued. The examiner is invited to telephone the undersigned if any matters remain to be resolved before the Notice of Allowance issues.

Respectfully submitted,

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